

REMARKS

In the Office Action under reply, the Examiner has rejected the claims as follows:

1. Under 35 U.S.C. §103(a) as obvious in view of PCT Publication WO 90/12579, hereinafter "Lange" (claims 12-17);
2. Under the judicially created doctrine of obviousness-type double patenting over claim 5 of commonly assigned U.S. Patent No. 6,632,801 (claims 12 and 13).

With the above amendments, claims 12 and 17 have been amended. Thus, claims 12-17 remain pending in the application.

The Examiner's rejections and objections are addressed, in part, by the above-amendments and are otherwise traversed by the arguments presented below.

THE AMENDMENTS TO THE CLAIMS:

Claims 12 and 17 have been amended to specify that the high molecular weight sulfated polysaccharide is prepared by sulfating a very high molecular weight polysaccharide with a sulfur containing compound. Support for this amendment can be found throughout the specification and is specifically disclosed on page 10, lines 4-13.

No new matter has been added to the application by way of these claim amendments.

REJECTION OF CLAIMS 1-24 UNDER 35 U.S.C. 103(A)

The Examiner has rejected claims 12-17 under 35 U.S.C. §103(a) as obvious in view of Lange. The reference is cited as teaching the administration of sulfated polysaccharides

as inhibitors of human cholesterol esterase to lower serum cholesterol and the co-administration of sulfated polysaccharides and other agents having cholesterol lowering activity. The Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the sulfated polysaccharides taught in Lange in combination with other agents, such as ACAT inhibitors or lovastatin. Further, the Examiner states that the ordinarily skilled practitioner would have been motivated to obtain the combined effect of the agents in lowering serum cholesterol with a reasonable expectation of success.

As amended, independent claims 12 and 17 recite a method for lowering serum cholesterol in humans comprising administering to a human the combination of

1. an essentially non-absorbable very high molecular weight sulfated polysaccharide and
2. a second compound that reduces serum cholesterol levels

wherein the high molecular weight sulfated polysaccharide is prepared by sulfating a very high molecular weight polysaccharide with a sulfur containing compound at a temperature less than about 20° C. As discussed in the specification, the recited method of preparing the very high molecular weight sulfated polysaccharide provides numerous advantages over previously known synthetic methods.

As the Examiner is aware, to establish *prima facie* obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success, and third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In the present case, the cited reference fails to establish *prima facie* obviousness as there is no teaching or suggestion in the reference of high molecular weight sulfated polysaccharide made by the recited synthetic method, i.e., wherein the high molecular weight sulfated polysaccharide is prepared by sulfating a very high molecular weight polysaccharide with a sulfur containing compound at a temperature less than about 20° C. The inventiveness of the recited method is further evidenced by the fact that method of treatment claims that recited the administration of high molecular weight sulfated polysaccharides made using the recited method were found patentable in the parent application, U.S. Patent No. 6,632,801.

The Examiner has also rejected dependent Claims 13-16. Applicants respectfully point out that Claims 13-16 are dependent claims that are subject to all of the limitations of independent Claim 12.

For the above reasons, reconsideration and withdrawal of the rejection of Claims 12-17 in view of Lange is respectfully requested.

THE OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION:

Claims 12 and 13 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of commonly assigned U.S. Patent No. 6,632,801 to Lange et al. In response to the obviousness-type double patenting issue raised by the Examiner, applicants are submitting a Terminal Disclaimer with the present communication, disclaiming the terminal portion of any patent issuing on the present continuing application that would extend beyond the term of U.S. Patent No. 6,632,801. Submission of this Terminal Disclaimer is not intended as acquiescence in the double patenting rejection, but is solely for the purpose of expediting prosecution.

Reconsideration and withdrawal of the rejection are accordingly in order and are respectfully requested.

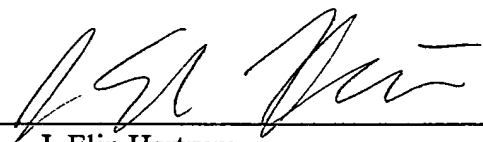
CONCLUSION

For the foregoing reasons, Applicant submits that the claims are in condition for allowance. A Notice of Allowance is requested, and a prompt mailing thereof would be much appreciated.

Should the Examiner have any questions, he is invited to contact the undersigned attorney at (650) 384-8755.

Respectfully submitted,

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By: 
J. Elin Hartrum
Reg. No. 43,663

CV Therapeutics, Inc.
3172 Porter Drive
Palo Alto, CA 94304
Tel: (650) 812-0585
Fax: (650) 475-0359

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APPENDIX A

CLEAN COPY OF CLAIMS AS AMENDED HEREIN

12. A method for lowering serum cholesterol in humans comprising administering to a human the combination of an essentially non-absorbable very high molecular weight sulfated polysaccharide having less than about 5.0 wt. percent of sulfated polysaccharides having a molecular weight less than 75,000 Daltons and containing less than 0.5 weight percent of inorganic sulfate and a second compound that reduces serum cholesterol levels wherein the high molecular weight sulfated polysaccharide is prepared by sulfating a very high molecular weight polysaccharide with a sulfur containing compound at a temperature less than about 20° C.

13. The method of claim 12 wherein the second compound is at least one cholesterol synthesis blocker.

14. The method of claim 13 wherein the cholesterol synthesis blocker is lovastatin.

15. The method of claim 12 wherein the second compound is an inhibitor of ACAT.

16. The method of claim 12 wherein the sulfated polysaccharide is sulfated cellulose.

17. A method for lowering serum cholesterol in humans comprising administering to a human the combination of an essentially non-absorbable very high molecular weight sulfated cellulose having less than about 5.0 wt. percent of sulfated cellulose having a molecular weight less than 75,000 Daltons and containing less than 0.5 weight percent of inorganic sulfate and lovastatin wherein the high molecular weight sulfated polysaccharide is prepared by sulfating a very high molecular weight polysaccharide with a sulfur containing compound at a temperature less than about 20° C.